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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,492

Applicant(s)

OLIVER ET AL.

Examiner

David A Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of a reply, filed January 2, 2003 as Paper No. 17, to the previous Office Action. Amendments were made to the claims.

Claims 1-12, 35, 37 and 38 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 14, mailed July 1, 2002, that is not addressed in this action has been withdrawn.

Because this Office Action only contains rejections maintained for reasons set forth in a previous Office Action or that are necessitated by amendment, this Office Action is made FINAL.

Drawings

New corrected drawings are required in this application because of the reasons set forth in the attached PTO-948 form. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: it is reiterated that the specification contains several errors, such as the misspelling of inducible as "inducible" throughout the specification; while applicant has amended the claims to address these

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informalities, the disclosure still contains numerous errors. Although applicant indicates in their response that a supplemental amendment will follow to correct these deficiencies, no such amendment has been received as of the date of mailing of this Office Action.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 35, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons set forth in the Office Action mailed July 1, 2002.**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 35, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is maintained for reasons set forth in the Office Action mailed July 1, 2002.**

Response to Arguments for Claim Rejections - 35 USC § 112

Applicant's arguments filed January 2, 2003 have been fully considered but they are not persuasive. Specifically, applicant argues that:

1. The use of the phrase 'functional derivatives' is justified by the contribution made to the art by the applicant.
2. The meaning of 'functional derivative' would be understood by one skilled in the art.
3. That it would be inequitable for a third party to avoid infringing Applicant's rights by simply introducing a trivial modification into the coding or non-coding sequence of *SRBI/PSAI* or *PKCI*, for example mutations that alter the sequence but not the function of one of the genes.
4. That because the *SRBI/PSAI* and *PKCI* genes (and mutations thereof) are known in the art, the ordinary skilled artisan would recognize functional derivatives of these genes, such as by comparison of base sequences.

These arguments are not found convincing for the following reasons:

1. The use of the phrase 'functional derivatives' is not justified by applicant's contribution. Applicant in no way provides any description of 'functional derivatives' of the *SRBI/PSAI* or *PKCI* genes. As applicant clearly indicates in their arguments (see for example page 4, first full paragraph), because the genes were both known in the art at the time of invention, applicant's contribution to the art is the operable association of these genes to heterologous promoters and their use to affect cell lysis, and not to the discovery or structure-function characterization of the genes. In order for applicant's contribution to justify the term 'functional derivatives', the specification would necessarily need to teach functional derivatives, which it does not. Again,

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there is no structure-function relationship described for either gene, functional domains of each gene are not demonstrated, and there is no description of what homologs from other organisms would possess the necessary activity (or complementation thereof) to be used in the invention. For this reason, the written description requirements have not been satisfied because the skilled artisan would not be able to envision 'functional derivatives' of either gene in the absence of the required structure-function relationships.

2. Although the meaning of the phrase 'functional derivative' may be known to the skilled artisan, it is unknown how it applies to the *SRBI/PSAI* or *PKCI* genes in the context of this invention, or in any other manner, since there is no description of a structure-function relationship for either gene product. Certainly, the skilled artisan would understand how to apply the term to a gene or gene product that has been characterized to demonstrate a structure-function relationship with another characterized gene. However, such a relationship was unknown for *SRBI/PSAI* and *PKCI* at the time of the instant invention, therefore the skilled artisan would not be able to apply the definition in the instant case.

3. It would also be inequitable for applicant to improperly hold the rights to an invention for which applicant has not made the appropriate contribution. In this instance, applicant has not made the necessary structure-function relationship determination in order to claim 'functional derivatives' of the *SRBI/PSAI* or *PKCI* genes. For example, another applicant may improve the activity of the *SRBI/PSAI* or *PKCI* genes by identifying the minimal domains and activities required for their role in maintaining the cell wall, thereby improving the instant invention by increasing the efficiency of the genes in this process. In a second example, an unknown gene with limited homology to either *SRBI/PSAI* or *PKCI* (e.g., homology to a single domain region,

but entirely different throughout the remaining gene product) might be identified and found to work well in (or improve) the instant invention. Without the structure-function knowledge in the instant specification that the homologous region between these genes was the only requirement for function in the instant invention, the ordinary skilled artisan could not envision that their gene would inadvertently infringe upon applicant's invention. These genes would certainly be considered 'functional derivatives', and are certainly not the result of trivial modifications, but instead the work of thorough investigation. If applicant were granted a patent for the existing claims, they would improperly hold the rights to these 'functional derivatives' although they have clearly not described them in the instant specification.

4. The fact that the genes were well known, thereby allowing a base comparison between sequences, does not equate into a description of a structure function relationship. It is well known in the art that simple sequence homology does not result in a predictable function. For example, when the Pendred protein was first identified, it was predicted that the protein served as a sulphate transporter based upon its sequence homology to a known family of sulphate transporters (see for example the Abstract, Everett *et al.*, *Nature Genetics* **17**: 411-422, 1997; see entire document; henceforth Everett). However, no biochemical or structure-function relationship was determined at the time to demonstrate this activity. In 1999, another group found that Pendred was not a sulphate transporter, instead serving as a chloride-iodide ion transporter despite the homology to sulphate transporters (see for example the Abstract, Scott *et al.*, *Nature Genetics* **21**: 440-443, 1999; see entire document; henceforth Scott). Scott further underscores the importance of establishing a function for sequences rather than predicting function based on homology (see for example page 441, left-side, third full paragraph), in light

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of their findings relative to those of Everett. These references undermine applicant's arguments that 'functional derivatives' can be established in the absence of a structure-function relationship because even when two genes are highly homologous, it is virtually impossible to accurately predict function.

In conclusion, applicant's arguments are not persuasive. The instant specification does not adequately provide a written description of a structure-function relationship for the *SRBI/PSA1* or *PKC1* genes. As a result, the skilled artisan would not be able to envision the invention to determine if they were improperly infringing upon applicant's rights while attempting to advance the art.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
March 3, 2003

DAVID GUZO
PRIMARY EXAMINER
